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Controversial vaccine studies: Why is Bill & Melinda Gates Foundation under fire from critics in India?

By KP Narayana Kumar, ET Bureau Last Updated: Aug 31, 2014, 03:47:00 PM IST

Synopsis
Bill & Melinda Gates Foundation has funded two entities that have played a key role in the immunization programme and are both under fire for conflict of interest.

In 2009, several schools for tribal children in Khammam district in Telangana — then a part of undivided Andhra Pradesh — became sites for observation studies for a cervical cancer vaccine that was administered to thousands of girls aged between nine and 15. The girls were administered the Human Papilloma Virus (HPV) vaccine in three rounds that year under the supervision of state health department officials. The vaccine used was Gardasil, manufactured by Merck. It was administered to around 16,000 girls in the district, many of whom stayed in state government-run hostels meant for tribal students.

Months later, many girls started falling ill and by 2010 five of them died. Two more deaths were reported from Vadodara, Gujarat, where an estimated 14,000 children studying in schools meant for tribal children were also vaccinated with another brand of HPV vaccine, Cervarix, manufactured by GSK. Earlier in the week, the Associated Press reported that scores of teenaged girls were hospitalised in a small town in northern Colombia with symptoms that parents suspect could be an adverse reaction to Gardasil.

A standing committee on health and family welfare that investigated the irregularities pertaining to the observation studies in India tabled its report a year ago, on August 30.

The committee found that consent for conducting these studies, in many cases, was taken from the hostel wardens, which was a flagrant violation of norms. In many other cases, thumbprint impressions of their poor and illiterate parents were duly affixed onto the consent form. The children also had no idea about the nature of the disease or the vaccine. The authorities concerned could not furnish requisite consent forms for the vaccinated children in a huge number of cases.

The committee said it was "deeply shocked to find that in Andhra Pradesh out of the 9,543 [consent] forms, 1,948 forms have thumb impressions while hostel wardens have signed 2,763 forms. In Gujarat, out of the 6,217 forms 3,944 have thumb impressions and 5,454 either signed or carried thumb impressions of guardians. The data revealed that a very large number of parents or guardians are illiterate and could not even write in their local languages, Telugu or Gujarati."

Earlier this month, taking a serious view of the death of seven tribal girls in the context of the observation studies, the Supreme Court asked the Drug Controller General of India (DCGI) and the Indian Council of Medical Research (ICMR) to explain how permissions were given.

The SC bench of justices Dipak Misra and V Gopala Gowda asked the Centre to produce relevant files that pertained to the grant of licence for trial of the HPV vaccine in India. The court also asked the Centre to appraise it of steps taken on the report of the parliamentary committee.

Shoddy Investigations

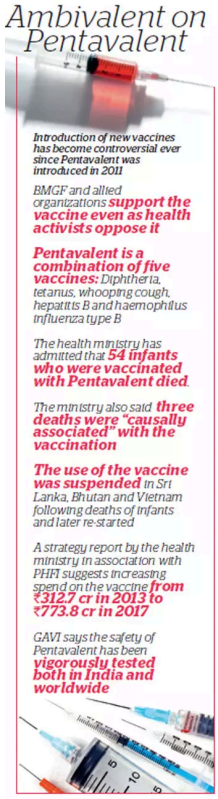
When a team of health activists from an NGO that specializes in women's health named Sama visited Khammam in March 2010 on a fact-finding mission, they were told that as many as 120 girls experienced adverse reactions such as epileptic seizures, severe stomach ache, headaches and mood swings. The Sama report also said there had been cases of early onset of menstruation following the vaccination, heavy bleeding and severe menstrual cramps among many students. The standing committee pulled up the relevant state governments for the shoddy investigation into these deaths. It said it was disturbed to find that "all the seven deaths were summarily dismissed as unrelated to vaccinations without in-depth investigations...the speculative causes were suicides, accidental drowning in well (why not suicide?), malaria, viral infections, subarachnoid hemorrhage (without autopsy) etc."

The committee said that in the context of deaths of girls classified as suicide, the role of the "HPV vaccine as a possible, if not probable, cause of suicidal ideation cannot be ruled out."

It said that an American NGO — Program for Appropriate Technology in Health (PATH) — had carried out the studies.

The committee found that the objective behind the observation studies in India primarily was to collect and record data on the effect of the vaccines on the minor subjects. Another objective was to help the relevant authorities in India make an informed opinion on introducing the vaccine into India's immunization programme. Providing a background, the report states that on June 1, 2006, American drug regulator, the US Food and Drug Administration (USFDA) approved the first vaccine — Gardasil — to prevent HPV. According to the World Health Organisation (WHO), two HPV types causes 70% of cervical cancers. In the very same month, PATH embarked upon a large-scale, five-year project that involved observation studies, covering Peru, Vietnam and Uganda, apart from India.

The committee observed that on November 16, 2006, a draft memorandum of understanding (MoU) between PATH and the ICMR was circulated by the latter. The MoU states that the two parties desire "...to explore collaboration to support public sector decision regarding HPV vaccine introduction in India and to generate necessary evidence to allow the possible introduction of HPV vaccine into India's Universal Immunization Programme." That idea appears to have hit a roadblock following the deaths of the children during the observation studies.



The standing committee report was a shocker but it became even more significant when it was mentioned that the study was sponsored by the Bill & Melinda Gates Foundation (BMGF).

Over the past decade, Bill Gates has transformed from an IT businessman into a global philanthropist. The foundation that he set up along with his wife is involved in hundreds of projects related to healthcare for the poor. Vaccination is a significant area of work and BMGF has projects running in almost every country that's counted as poor. BMGF continues to partner PATH in a number of studies such as the ones for a Rotavirus vaccine and pneumococcal vaccine in several countries, mainly Africa and Asia.

The health ministry also has not stopped PATH, in any manner, from becoming a part of such studies in India. The NGO has been roped in for other vaccine observation studies in India wherein it partners the department of bio-technology and other government departments. Health secretary Lov Verma refused to give an answer when ET Magazine asked why PATH continued to be allowed to carry out observation studies in India even after the studies which allegedly turned fatal.

According to the BMGF, the WHO, the International Federation of Gynaecology and Obstetrics, and the Federation of Obstetric and Gynaecological Societies of India have all recommended vaccination "as a proven and highly effective preventive measure for cervical cancer. "The project used vaccines that are licensed in India and that have been administered safely around the world tens of millions of times, preventing countless cases of cervical cancer illness and death," maintains a BMGF spokesperson in an emailed response (see GAVI & PHFI create incentives...).

The Wrong PATH

BMGF's role in funding the controversial studies, however, has led to many healthcare activists in India voicing their apprehensions. "BMGF has to take full responsibility because PATH is funded by them. It is also unethical when people championing the cause of vaccines are the same ones who are also investing in vaccine development," said V Rukmini Rao, one of the activists who filed a writ petition before the Supreme Court in connection with the HPV vaccine studies.

BMGF has funded two organizations that over the past five years have played a significant role in the country's immunization programme and are both under fire for conflict of interest. The organizations are GAVI (earlier known as Global Alliance for Vaccines and Immunization), a global aid organization that specializes in vaccination, and Public Health Foundation of India (PHFI), a public-private partnership society that BMGF co-founded with the UPA government in 2006.

Activists allege that these two institutions have a working relationship with pharma companies. The main charge against GAVI is that it has representatives from pharmaceutical companies on its board while the PHFI accepts grants from pharma companies. "BMGF and GAVI are pushing the [vaccine] agenda with governments around the world, including India," says Ritu Priya Mehrotra, professor of Social Medicine and Community Health and School of Social Sciences, Jawaharlal Nehru University, Delhi. The community health activist says the biotechnology industry was pushing more and more vaccines into India and that the health ministry was not ensuring that adequate testing was done before recommending their use in government programmes.

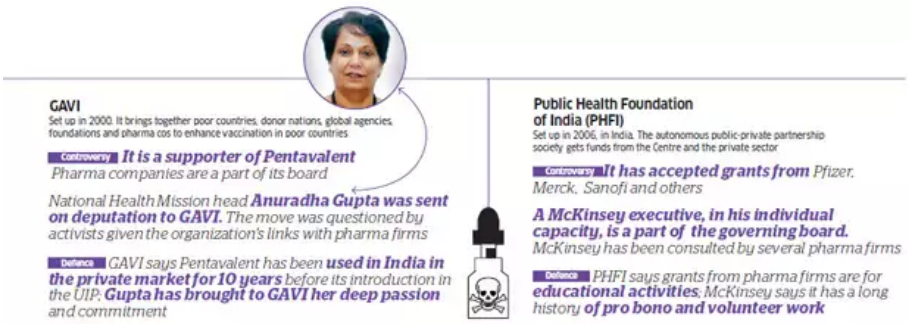
"We need to follow the precautionary principle when it comes to vaccines. We do need more vaccines...but we should ensure that enough time is given for research to prove the efficacy and safety of new vaccines. The vaccines that are to be brought here should also fit our epidemiological profile," adds Mehrotra. Mehrotra adds that a network of people in aid agencies and the health bureaucracy were pushing this agenda. "They have the advantage of an existing medicalized mindset that believes vaccines are the perfect, safe, effective, low-cost solution for prevention of infectious diseases. There is ample evidence that this is not always the case."

The current trend is to dilute safety testing criteria and cut short on time required to conduct proper observation studies. "The best example is the Pentavalent vaccine against which there is evidence to be wary of and yet we are going ahead [with its use in the immunization programme]," points out Mehrotra.

Wrong Dose

In recent years, the deaths of many infants allegedly soon after they were immunized with the Pentavalent vaccine, a five-in-one shot, has contributed towards anxiety around vaccines. The vaccine has been controversial in Sri Lanka, Bhutan and Vietnam, too, where it was temporarily suspended on account of some reported post-vaccination deaths of infants.

Launched in 2011 in India, Pentavalent is a combination of five vaccines in one: diphtheria, tetanus, whooping cough, hepatitis B and haemophilus influenza type b (the bacteria that causes meningitis and pneumonia). The vaccine created a furore after many infants from across the country were reported to have died after the vaccination. A reply by the health ministry to an RTI application shows that the deaths of three infants in Tamil Nadu have "a consistent causal association to immunization", which means the ministry confirms that there is a connection between the vaccination and the deaths. In all, 54 cases of deaths of infants who were vaccinated with Pentavalent have been classified as 'adverse events following immunization'(AEFI), nomenclature that confirms the deaths have occurred soon after vaccination.



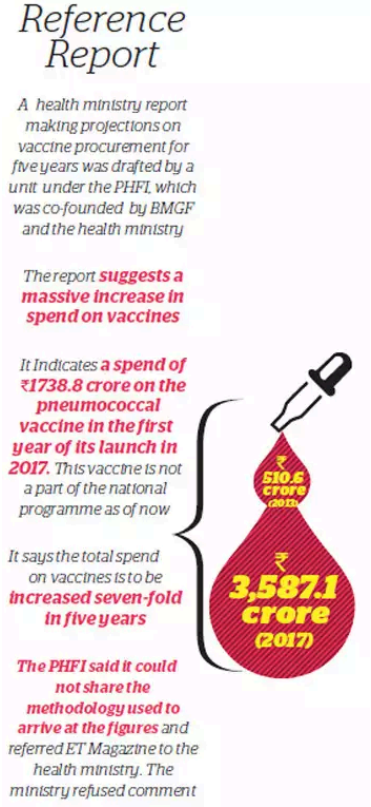
ET Magazine's questionnaires to the health secretary were unanswered. BMGF, GAVI and PHFI are in favour of Pentavalent even as a number of paediatricians and health experts have petitioned the government to take a second look at the vaccine in light of the deaths of infants.

In an opinion piece published recently in Deccan Herald titled "New Vaccines: Gates Foundation's philanthropy or business?", Dr Gopal Dabade of the All India Drug Action Network said that GAVI had committed a $165-million grant for the phased introduction of Pentavalent in India and provides a subsidy of Rs 145 per injection for five years after which the government will have to pay the total cost of the vaccines. "BMGF is a founding partner of GAVI. Its initial grant helped establish GAVI and it continues to support its work. Some of the pharmaceutical companies have affiliation with BMGF to manufacture the vaccine," Dr Dabade said.

The Controversial Report

A recent strategy document on immunization published this year by the health ministry suggests doubling the expenditure on purchase of Pentavalent. The Multi-Year Strategic Plan for the Universal Immunization Programme (UIP) makes the case that the ministry needs to double its spend on Pentavalent from Rs 312.7 crore in 2013 to Rs 773.8 crore in 2017. The report also calls for a seven-fold increase in total spend on vaccines — from Rs 510.6 crore to Rs 3,587.1 crore by the same year.

The report was drafted by a team of immunization researchers who work under the PHFI which was co-founded by BMGF and the UPA government as a public private partnership. A few experts from UNICEF and WHO were also part of the team. Interestingly, its on the basis of such multiyear plans that GAVI, also funded by BMGF, disburses grants to countries.



Started in 2000, GAVI is a first-of-its kind funding agency that brings together poor countries, donor nations, global agencies, foundations, individual donors and pharma companies to enhance vaccination in poor countries. The funding is split between governments of the developed world (74%) and corporations, foundations and individuals (26%). BMGF accounts for about a fifth of the total contributions. The HPV vaccine, used as a part of the allegedly fatal observational studies in undivided Andhra Pradesh and Gujarat, as well as Pentavalent are both part of a range of vaccines that countries can seek co-financing support for under GAVI's scheme for new and underused vaccines.

The GAVI board comprises of a representative each of the pharma industry from the industrialized and developing countries, a sore point with some experts from the aid world. In an article in the The Guardian three years ago, leaders of international aid agencies such as Oxfam and MSF said the representatives of companies needed to step down from the GAVI board. "Pharmaceutical companies' representation on GAVI's board creates a conflict of interest. The current structure is far too cosy," said the article quoting Mohga Kamal-Yanni, a senior policy adviser with Oxfam.

In a statement to ET Magazine, GAVI defended its model: "As a public-private partnership, GAVI harnesses the capabilities of the public and private sector to maximise its impact on health and development. While we believe this model is critical for our mission, we also recognize that it requires us to manage potential conflicts of interest. Therefore, relationships with the private sector are managed through strict policies. For instance, a board member representing manufacturers will be asked to leave discussions and be excluded from voting on any issue where a potential conflict of interest is identified."

Recently, an additional secretary with the health ministry, Anuradha Gupta, was appointed as the deputy CEO of GAVI. Gupta was earlier in charge of the National Health Mission. Healthcare activists raised a furore as the international

agency's board also has representation from pharmaceutical companies. The Alliance Against Conflict of Interest, an organization fighting for a legislation on the subject, highlighted Gupta's move from government to GAVI as an example.

GAVI's defences is that "Ms Gupta has brought to GAVI her deep passion and commitment to protecting maternal and child health which includes enabling them to access life-saving vaccines. She strongly supports GAVI's vision and mission which is to save children's lives and protect people's health by increasing access to immunization in poor countries."

Conflict of Interest

Similar controversies on proximity with pharma companies and conflict of interest have been raised about PHFI. While PHFI is engaged in public health and is also partnering the government in UIP, it has accepted grants from a number of pharma companies, including vaccine manufacturers. In all, PHFI has accepted grants worth around `57.65 crore from pharma companies, including Merck Sharp and Dohme, Pfizer and Sanofi, which manufacture vaccines. Sanofi is one of the many manufacturers of the controversial Pentavalent vaccine around the world.

PHFI head K Srinath Reddy asserts that the grants "that the PHFI has received from pharmaceutical companies are meant for broader educational activities, and are not intended to benefit PHFI, a pharma company or any other specific organization."

Another point that provides firepower to the critics is PHFI's McKinsey connection. An executive with the consulting company, Gautam Kumra, is present on the governing body of PHFI. Kumra's profile on McKinsey's website declares that his areas of expertise include healthcare. He is also credited with helping "one of India's leading pharmaceutical companies define its 10-year vision, redesign its organization and upgrade its capabilities to execute the vision."

In 2012, McKinsey published a report titled "Transforming India's vaccine market" in association with the Organisation of Pharmaceutical Producers of India.

The report suggests that India's vaccine market is much smaller and underpenetrated than its global peers and discusses impediments that have hampered growth of the vaccine market. The report also features a scenario as per which the optimistic case would be that the market would have hit a value of around $3.2 billion in 2020, growing at 30-35% year-on-year from 2012 onwards. "In all likelihood, there will be five "mega" vaccines of over $250 million each in size, constituting 60% of the market, namely the anti-influenza, anti-typhoid, HPV, pneumococcal and Hepatitis A," the report said.

A McKinsey spokesperson said "the consultancy does not have a working relationship with PHFI. Gautam Kumra, a senior partner at McKinsey & Company, is a member of PHFI's governing board but in an entirely personal capacity as a healthcare systems expert and not as a representative of McKinsey." The consultancy also said it had a long history of pro bono and volunteer work for private, public and social sector organizations.

Public health activist and pediatrician Dr Arun Gupta says PHFI's links with pharma companies and McKinsey are unacceptable. "It is a clear conflict of interest. Neither the government nor PHFI has come out clearly and spoken of their relationship with each other... it seems to be a private club that helps pharma companies make inroads into public policy."

Funding PHFI: What the Companies Say

Sanofi
Our partnership with PHFI in the area of diabetes for KiDS [Kids and Diabetes in Schools] is one of our numerous partnerships – both globally and in India

Merck
MSD has no influence or say in the design, construct or running of the [grant] programme.... We have no programme or grant with PHFI for vaccines

Pfizer
We recommend that you connect directly with PHFI

"PHFI is a private society cleverly disguised as a public-private partnership since some of the people in the governing body are or have been senior civil servants or public servants," adds Supreme Court lawyer and activist Prashant Bhushan. Bhushan points out that PHFI appears to have several connections with the big pharma companies and their consultants. "The PHFI appears to have a conflict of interest in advising the government of India and directing the immunization programme."

PHFI's Srinath Reddy stresses that they had received unrestricted educational grants from pharma companies towards

building the capacity of health professionals for providing appropriate health care of adequate quality in primary health care settings. However, these were not connected with the PHFI's work on the immunization front, he added. "As a not-for-profit organization, PHFI receives grants from different stakeholders for funding capacity building programmes which address broader public health and health system needs, including quality of healthcare. These grants are in no way tied to any pharmaceutical product and are meant solely for educational activities." But then again the line between transferring medical knowledge and deriving commercial interests is a thin one.

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